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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/535,220	05/17/2005	Juan Carlos Domingo Pedrol	OFICINA PONTI-256731	9405

21831 7590 03/02/2011

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EXAMINER	
ZAREK, PAUL E	

ART UNIT	PAPER NUMBER
1628	

NOTIFICATION DATE	DELIVERY MODE
03/02/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

pto@cozen.com
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Office Action Summary	Application No.	Applicant(s)	
	10/535,220	DOMINGO PEDROL ET AL.	
	Examiner	Art Unit	
	Paul Zarek	1628	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 August 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *16-22 and 25-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *16-22 and 25-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 08/25/2010 has been entered.

Status of the Claims

2. Claim 16 has been amended by the Applicant in correspondence filed on 08/25/2010. Claims 16-22 and 25-28 are currently pending. This is the first Office Action on the merits of the claim(s) following a second request for continued examination.

RESPONSE TO ARGUMENTS

3. The Advisory Action mailed on 07/06/2010 indicated Applicants' after-Final amendment would not be entered, in part, because it raised the issue of new matter regarding the limitation that DHA is the only active substance in the administered composition. Applicants note that the specification relates to the use of DHA "as active substance" (specification pg 3, ln 20-24) which denotes that there is only one active substance. If more than one active substance were permitted by the specification, Applicants' argue, the article "a" or "an" would have preceded "active

substance." Examiner finds Applicants' argument persuasive and the claim amendment "as the only active substance" has written support in the specification. There is no issue of new matter.

4. Claims 16-22 and 25-28 were rejected under 35 U.S.C. 102(e) as being anticipated by Pacioretty and Babish (US PreGrant Publication No. 2004/0106591, which claims the benefit of provisional application 60/428,246, filed on 11/22/2002, already of record). This rejection is moot in light of Applicants' amendment to Claim 16.

5. Claims 16-22 and 25-28 were rejected under 35 U.S.C. 103(a) as being unpatentable over Holstein, et al. (Experimental and Clinical Endocrinology and Diabetes, 2001), in view of Connor, et al. (Annals of the New York Academy of Sciences, 1993). Applicants traversed the rejection on the grounds that this combination of prior art does not teach or fairly suggest the claimed invention. Specifically, Applicants contend that there is a difference between hyperlipidemia and lipodystrophy. Applicants submit various journal articles as evidence that lipodystrophy involves multiple systems (i.e. reduction in HDL, increase in LDL, insulin resistance, etc) and that treating one or some symptoms of lipodystrophy is not the same thing as treating lipodystrophy itself. Applicants assert that the claimed invention treats the lipodystrophy itself, not a symptom thereof. Respectfully, Examiner does not find Applicants' argument persuasive.

6. Examiner disagrees with Applicants' contention that treating a symptom of a disease does not fall under the scope of treating the underlying disease itself. Stedman's Medical Dictionary defines "treat" thusly: "to manage a disease by medicinal, surgical, or other measures; to care for a patient medically or surgically." There is no distinction in the definition between affecting a symptom of a disease and the disease itself. As discussed previously, lipodystrophy is a defective

metabolism of fat and hyperlipidemia is a result of this defective metabolism. Hyperlipidemia is reasonably construed as a symptom of lipodystrophy. Treating hyperlipidemia in a subject that suffers lipodystrophy (hyperlipidemia is almost always associated with lipodystrophy) is the management of lipodystrophy, which falls under the scope of "treat" as define by Stedman's Medical Dictionary.

7. Holstein, et al., teach that HAART causes lipodystrophy and hyperlipidemia (abstract). Connor, et al., teach that n-3 fatty acids (i.e. DHA) from fish oil has "profound hypolipidemic effects" in hypertriglyceridemic patients with hyperlipidemia (abstract). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to use a composition known to treat lipodystrophy (DHA) as a therapy for lipodystrophy, which is a known complication of HAART in HIV-infected patients. Therefore, the rejection of Claims 16-22 and 25-28 under 35 U.S.C. 103(a) as being unpatentable over Holstein, et al., and Clinical Endocrinology and Diabetes, 2001), in view of Connor, et al., is maintained.

Conclusion

8. Claims 16-22 and 25-28 remain rejected.

9. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul Zarek whose telephone number is (571) 270-5754. The examiner can normally be reached on Monday-Thursday, 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brandon Fetterolf can be reached on (571) 272-2919. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

PEZ

/San-ming Hui/
Primary Examiner, Art Unit 1628